HIMA

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

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November 1, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Draft Guidance: Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval (Docket Number 99D-2167)

Dear Sir or Madam:

The Health Industry Manufacturers Association (HIMA) hereby submits its written comments on the Draft Guidance: "Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval" (hereafter, Guidance). The Notice of the Draft Guidance's availability was published in the *Federal Register*. See 64 Fed. Reg. 42700 (August 5, 1999).

HIMA is the largest medical technology trade association in the world. It has more than 800 member firms that manufacture medical devices, diagnostic products and health information systems. HIMA members provide nearly 90 percent of the $62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $147 billion purchased annually around the world.

HIMA appreciates FDA working with the Medical Device Industry Initiative Grassroots Task Force to develop the Guidance. HIMA believes the Guidance will help firms to reduce the regulatory burden when they implement a manufacturing change and clarify the circumstances under which an FDA inspection will occur.

General Comments

HIMA believes that the document is well written and will be easy for both FDA and industry officials to understand. The flow diagram, followed by the narrative, provides clarification and specific situations that are applicable to the 30-Day Notice or the 180-Day Notice.

Specific Comments

1) The Guidance on page 5, under the heading titled, "Changes in Manufacturing Methods or Procedures," says, " FDA will not normally conduct inspections as part of the review of 30-Day Notices or 135-day Supplements (emphasis added)." In fact, FDA cannot, nor should they try to, conduct an inspection on a 30-Day Notice. Additionally, FDA can and should

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specify the conditions when the agency is likely to conduct an inspection for a 135-day supplement. HIMA believes that such conditions should be extremely limited.

2) The Guidance on page 6, under the heading titled, "Changes to the Device or its Labeling," refers to a "30-Day PMA Supplement – Changes Being Effected." HIMA believes that the correct terminology should be "Special PMA Supplement – Changes Being Effected" in accordance with 21 CFR 814.39(d).

3) HIMA believes that step G2 in the flow chart on page 7 should be changed. For a change to a device with "similar indication for use, mode of operation, and technological basis of operation as the currently approved device, " the flow chart requires a 180-day supplement. This is incorrect. The arrow should point to the box "See Modifications to Devices Subject to Premarket Approval – The PMA Supplement Decision Making Process." Currently this Guidance refers to the "PMA Supplement Decision Making Process" document for changes that only involve labeling. The "PMA Supplement Decision Making Process" document deals with design changes, and this correction is necessary to make these two FDA documents consistent.

4) HIMA supports the concept expressed in the flow chart on page 7 that will allow, under certain conditions, the transfer of devices to facilities already manufacturing other medical devices without FDA pre-approval inspection. However, the test (specifically page 4, paragraph 3 under the "Background" section and pages 5-6, paragraph 1 under "Changes in the Locations of Manufacturing Facilities") suggests that the only moves that qualify for this process are when a manufacturer moves to a totally new facility. Also, the language suggests that only those manufacturers who establish new facilities understand how to transfer products without problems. Since this is not what is reflected in the flow chart, the language in the paragraphs referred to above on pages 4 and 5-6 should be changed to be consistent with the flow chart.

5) The Guidance under the explanation of E2 on page 8 provides examples of changes to manufacturing methods or manufacturing procedures that could potentially affect the safety and effectiveness of the device including "...vendors of material, where specifications of the material are unchanged." HIMA suggests that this condition be modified to include "vendors of materials where the materials directly contribute to the proper functioning of the device and a change in materials would likely affect safety and effectiveness of the functioning of the device."

6) The Guidance on page 9 the second paragraph under F4 states:

> If the manufacturing process for the device under consideration has not been validated within the last year, it may also be necessary to revalidate the complete process after the move.

HIMA suggests that this sentence be deleted because this deals with validation requirements unrelated to the subject of the paragraph (change of a manufacturing facility) which is the section being discussed.

7) The Guidance on page 10 under G3 states:

> You should also consult with the appropriate division if there will be a change in the patient population that will be treated with the device.

HIMA suggests that this sentence be removed because a change in the patient population constitutes a change in the indications; and this change was covered in the previous sentence.

Respectfully submitted,

Nancy Singer
Special Counsel

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